Clinical Policy Title: **Rilonacept (Arcalyst)**

Policy Number: **RxA.16**

Drug(s) Applied: **Rilonacept (Arcalyst®)**

Last Review Date: **05/2020**

Line of Business: **Commercial, HIM, Medicaid**

Background

Rilonacept (Arcalyst®) is an interleukin-1 blocker.

Arcalyst is indicated for the treatment of cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS) in adults and children 12 and older.

Indication	Dosing Regimen	Maximum Dose
CAPS (FCAS, MWS)	Age ≥ 18 years: 320 mg SC loading dose followed by 160 mg SC once weekly Age 12 to 17 years: 4.4 mg/kg SC loading dose followed by 2.2 mg/kg SC once weekly	Loading dose: 320 mg; Maintenance dose: 160 mg weekly

Single-use vial for reconstitution: 220 mg (each reconstituted vial delivers 160 mg)
Begin maintenance dose 1 week following loading dose. Do not administer more than once weekly.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Cryopyrin-Associated Periodic Syndromes (must meet all)**:**

1. Diagnosis of FCAS or MWS;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 12 years;
4. Dose does not exceed a loading dose of 320 mg (as two injections on same day at 2 different sites) and once weekly dosing of 160 mg (as a single injection).

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

II. Continued Therapy

A. Cryopyrin-Associated Periodic Syndromes (must meet all)**:**

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed once weekly dosing of 160 mg (as a single injection).

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer.

III. Appendices

Appendix A: Abbreviation/Acronym Key

CAPS: Cryopyrin-Associated Periodic Syndromes
FCAS: Familial Cold Autoinflammatory Syndrome
FDA: Food and Drug Administration
MWS: Muckle-Wells Syndrome

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information

- Three related conditions make up the broader disease known as CAPS: FCAS, MWS, and neonatal-onset multisystem inflammatory disease (NOMID), also known as chronic infantile neurologic cutaneous articular syndrome (CINCA). Arcalyst is not FDA approved for use in patients with NOMID/CINCA.
- Concomitant administration of Arcalyst with tumor necrosis factor (TNF) inhibitors (e.g., Enbrel, Humira, or Remicade) and interleukin-1 blocking agents (e.g., Kineret) is not recommended because this may increase the risk of serious infections.
- Examples of positive response to therapy include reduction/normalization of: C-reactive protein levels, serum amyloid A levels, flare frequency, or severity and duration of symptoms (e.g., joint pain, rash, fever/chills, eye pain, fatigue).
- Do not initiate treatment with Arcalyst in patients with active or chronic infections.

References

1. Arcalyst Prescribing Information. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; September 2016. Available at https://www.regeneron.com/sites/default/files/Arcalyst_FPI.pdf. Accessed February 26, 2019.
2. Hoffman, HM, Throne ML, Amar NJ, et al. Efficacy and safety of rilonacept (interleukin-1 trap) in patients with cryopyrin-associated periodic syndromes. Arthritis and Rheumatism. 2008;58(8): 2443-2452
3. Arcalyst (rilonacept) [package insert]. Tarrytown, NY; Regeneron; Revised 02/27/2008.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Policy updated – added clarifying information regarding dosing and administration.	05/2020	05/21/2020